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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,591	02/15/2002	James Larkins	DEKA:299US	1557

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/077,591

Applicant(s)

Larkin's

Examiner

FOX

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/21/03
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-31 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 1-15 and 17-23 is/are allowed.
- ☒ Claim(s) 16 and 24-31 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendments of 21 April 2003 and accompanying declaration have overcome the objections to the specification and the claims, and the enablement rejection with regard to a deposit.

Claims 16 and 27-30 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as stated on page 2 of the last Office action.

Claims 16 and 24-31 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 3-5 of the last Office action.

Claims 16 and 24-31 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on pages 5-7 of the last Office action.

Claim 31 remains rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cummings et al (U.S. 5,977,455), as stated on pages 10-11 of the last Office action.

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Claims 1-30 remain free of the prior art, given the failure of the prior art to teach or suggest an inbred corn plant with the unique genetic and morphological complement of the exemplified corn plant, or methods of its use for classical breeding or transformation.

Claims 1-15 and 17-23 are allowed.

Applicant's arguments filed 21 April 2003, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the indefiniteness rejections are improper, given the proper further limitation by claims 16 and 27-30 of the claims from which they depend.

The Examiner maintains that the independent claims from which they depend are drawn to a maize plant with a particular set of characteristics and a particular allele at every genetic locus. Thus, to later claim a plant which has even one different characteristic and a different gene or allele at even one locus fails to further limit the independent claims, since the dependent claims negate the characteristics of the plant of the independent claim, rather than merely adding to them. For example, rendering the male fertile plant of claim 15 as simultaneously male sterile (as recited in claim 16) fails to further limit the original plant. Applicant is directed to the suggested claim amendments provided in the last Office action.

Applicant urges that the written description rejection is improper, given the description in the specification of a hybrid using the exemplified inbred as a parent, the disclosure of molecular markers found in both the inbred and the hybrid, the conservation of the same half of the genetic contribution from the exemplified inbred parent in all recipient hybrids, and the disclosure of many

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transgenes or single gene conversions in the specification. Applicant urges that the written description rejection of claim 31 is improper, since all of the essential steps have been recited and described.

The Examiner maintains that the claims are not limited to the exemplified hybrid, which single hybrid is admittedly adequately described. Regarding the molecular markers, it is noted that the SSR markers and isozyme markers found in the inbred have been retained by the exemplified hybrid. However, many of the individual markers, particularly the SSR markers, were not unique to the exemplified inbred (see, e.g., Table 6, page 62 of the specification, rows 2-4, 7, 9-10, 12, 14-16, 19-20, 22-23 etc). Since Applicant has not provided any actual characterization of the entire genome of the exemplified inbred at every locus, and since Applicant has not indicated which SSR or isozyme marker is associated with which trait exhibited by the exemplified inbred, Applicant has not disclosed any structural features which are correlated with function and which would be common to the genomes of all hybrids derived from the inbred.

Regarding the transgenes or single gene conversions, Applicant has not provided any structural sequences common to all of the transgenes or single gene conversions which were correlated with function. Furthermore, Applicant has not described any transformed or single gene converted-inbred plant which would retain all of the features of the exemplified inbred except for the introduced transgene-encoded or single gene conversion-encoded trait. Applicant has only described the exemplified inbred with respect to a collection of traits. It is unclear how the introduction of a multitude of non-exemplified transgenes or single gene conversions,

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encoding a multitude of proteins or enzymes or inhibitory RNA products which would be involved in a multitude of metabolic pathways resulting in a multitude of traits, would interfere with one or more of these traits. Such interference would result in the production of a multitude of corn plants with a different collection of traits than the exemplified inbred. Since the only identifying description of the exemplified inbred, namely the unique collection of traits, has now been obliterated, the genus of corn plants containing a multitude of non-exemplified transgenes or single gene conversions would be inadequately described. It is noted that claims limited to a method of producing a transgenic corn plant comprising transforming the exemplified inbred with single, known transgenes recited in the specification, and the resultant corn plant produced by that process, would in fact be adequately described, as stated in the last Office action.

Regarding claim 31, the use of multiple inadequately described products, i.e. plants resulting from outcrosses of the exemplified inbred with a multitude of undescribed second parents, in a method renders that method inadequately described, per the Revised Written Description Guidelines cited on pages 4-5 of the last Office action.

Applicant urges that the remaining enablement rejection is improper, given the disclosure in the specification of various means of corn plant transformation, the disclosure of a single gene conversion plant in the specification, the lack of relevancy or persuasiveness of the references cited by the Examiner to support his position, and the enablement in the specification of methods of corn hybridization.

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The Examiner maintains that the ability to produce transformed corn plants in general is not disputed. Rather, the specification fails to enable the production of corn plants which would be identical to the exemplified inbred except for a single trait, following the introduction of a multitude of non-exemplified transgenes encoding products involved in a multitude of metabolic pathways which would affect a multitude of traits.

Regarding the exemplified method of incorporating cytoplasmic male sterility into the exemplified inbred, following seven generations of backcrossing to the exemplified inbred, as set forth on pages 35-36 of the specification, it is noted that the claims do not recite this procedure or plants produced by it. Furthermore, the subsequently obtained single gene conversion plant set forth in the specification was not evaluated for the retention of all of the traits found in the initial inbred which confer patentability thereto. Due to linkage drag and other factors as set forth in the last Office action, it is unpredictable that all of the traits of the inbred would be retained following the initial outcross to the male sterile parent, even after seven generations of backcrossing. Since the individual traits of the exemplified inbred are not unique to it, the collection of traits it exhibits must not be disturbed. It is this aspect that mandates the enablement rejection. Applicant is invited to provide evidence in the form of a Rule 132 declaration that the exemplified single gene conversion plant set forth on pages 35-36 of the specification was subsequently evaluated for every trait (and its degree of expression) listed in Tables 2 and 3 of the specification, with the exception of male fertility. Such a demonstration would lead to the removal of this rejection and

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the written description rejection above, as applied to the issue of single gene conversions, following any additional claim amendments deemed necessary.

Regarding the references cited by the Examiner, the Examiner maintains that the references do in fact demonstrate the unpredictability inherent in the process of introgressing single traits into various plants of different genetic backgrounds, and the unpredictability inherent in utilizing molecular breeding techniques in crop plants. The fact that these references are not specific to corn is immaterial. The references demonstrate the widespread phenomenon of unpredictability throughout cultivated plant species, and Applicant has not provided any guidance or evidence to overcome this unpredictability.

Regarding the claims drawn to hybrids, the Examiner maintains that in the absence of a disclosure of the second parent, or the limitation in the claims to a particular second parent or a particular hybrid product, and in the absence of any disclosure of the traits exhibited by the resultant hybrid, one skilled in the art would not know how to use said hybrid.

Applicant urges that the art rejection is improper, given the failure of the prior art to teach or suggest the use of the exemplified inbred as a starting material. The Examiner maintains that given the recitation of multiple generations of outcrossing with a multitude of non-exemplified breeding partners, the resultant product plant would lose the genetic material from the starting material and be indistinguishable from the prior art plant, and so properly rejectable per *In re Thorpe* cited previously.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 27, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

